

REMARKS

In response to the restriction requirement, Applicants elect Group I (claims 1, 2, 16, and 17), with traverse.

In the event that the Examiner insists upon only examining one of the claimed polypeptides, and therefore requires that only part of Applicants' claims be elected, Applicants hereby provisionally elect the claims directed to the portion of claims 1, 2, 16, and 17 directed to the polypeptide of SEQ ID NO:1, and the variants and fragments thereof as presently claimed, with traverse. The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 7th edition of the M.P.E.P. (July 1998) at § 803.02 regarding restriction requirements in Markush-type claims:

PRACTICE RE MARKUSH-TYPE CLAIMS

If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The

provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First, the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure

described below and will not require restriction.” Withdrawal of the restriction requirement as among the three specific sequences each in the claims is required on that basis alone.

Second, it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. ... Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**” Clearly, the three polypeptides of the instant invention, and polynucleotide sequences encoding them, share both a common utility and structural homology, based on their classification as vesicle trafficking proteins.

Third, even if the claims could be considered to be “Markush-type generic claims which include a plurality of alternatively usable substances or members,” it is further noted that the M.P.E.P states that “A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits.” This clearly applies in the present case.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:1 and finding no prior art over which SEQ ID NO:1 can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species.

Applicants further suggest that the invention encompassed by the claims of Groups I and III, drawn to polypeptides and antibodies to the polypeptides, respectively, could be examined at the same time, also without undue burden on the Examiner. A search of the prior art to determine the novelty of the antibodies would substantially overlap with a search of the claims directed to the polypeptides.

Applicants further suggest that the claims of Group V are methods of use of the polypeptides of Group I (claims 1, 2, 16, and 17), which should be examined together, per the Commissioner’s Notice in the Official Gazette of March 26, 1996, entitled “Guidance on Treatment of Product and

Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products. Applicants respectfully submit that there is minimal additional burden on the Examiner to examine those claims in addition to the claims elected in the present application.

Accordingly, because the searches required to identify prior art relevant to the claims of Groups I, III, and V would substantially overlap, Applicants respectfully submit that examination of all of these claims together would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of the claims.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

This form is enclosed in duplicate.

Respectfully submitted,

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Date: June 6, 2001

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